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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,426	09/27/2001	Marcus C. Merriman	47097-01106USC1	4436
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JENKENS & GILCHRIST, P.C. 225 WEST WASHINGTON SUITE 2600 CHICAGO, IL 60606				EXAMINER MADSEN, ROBERT A
				ART UNIT 1761 PAPER NUMBER

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/965,426	Applicant(s) MERRIMAN ET AL
	Examiner Robert Madsen	Art Unit 1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office after the three-month period from the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 March 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 38-56 and 76-168 is/are pending in the application.
- 4a) Of the above claim(s) 87-118, 122, 141 and 160 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 38-56, 76-86, 119-121, 123-140, 142-159 and 161-168 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a)
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of species b an impermeable layer attached to a permeable layer in the Response filed March 5, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 38-56 and 76-168 remain pending, with claims 87-118,122,141, and 160 being withdrawn from further consideration as being directed to a non-elected species.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 38, 40-56, 76, 78-86, 119, 121, 123-138, 140, 142-157, 159, 161-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockley III et al. (US 5686127) in view of Woodruff et al. (US 4522835).

4. Stockley et al. teach supplying a first polystyrene foam tray as recited in claims 41,51,79,84,123,132,142,151,161,166 placing a retail meat in the tray, preferably removing oxygen to less than 0.5%, or even less than 0.05% (or less than 500 ppm, as recited in claims 44,45,81,82,125,126,144,145,163,164), to inhibit or prevent the formation of metmyoglobin by gas flushing with carbon dioxide and/or nitrogen as

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recited in claims 47,48,50,128,129,147,148, or alternatively removing oxygen by vacuum as recited in claims 46,127,146, sealing the tray with a first oxygen permeable layer polyolefin overwrap as recited in claims 52,133,152,157, sealing a second oxygen impermeable layer to the first layer wherein the second layer is peelably removable from the first layer, as recited in claims 40,78,121,140,159, and removing the second layer without removing the first as recited in claims 38,76,157, to expose for retail display, as recited in claim 42, 119,138 (Column 1, lines 1-62, Column 5, lines2-8, 32-36, Column 7, lines 8-30, Column 8, lines 23-64).

5. Stockley et al. are silent in teaching in teaching 0.1-0.8%,0.3-0.5% , or 0.1-0.5%, carbon monoxide in addition to the carbon dioxide and nitrogen or just carbon dioxide to form carboxymyoglobin, as recited in claims 38,50,55,56,76,85,86,119, 131,136, 137, 138, 150,155,156,157,167,168, using an oxygen scavenger as recited in claims 43,80,124,143,162, converting deoxymyoglobin directly to carboxymyoglobin as recited in claim 54,135,154 or oxymyoglobin to carboxymyoglobin as recited in claim 53,134,153, and the particular level of carbon dioxide and nitrogen in combination as recited in claims 49, 83, 131,149, 165.

6. Woodruff et al. also teach meat that is stored in a refrigerated or frozen state under low oxygen conditions prior to final sale/consumption packaging. Woodruff et al. teach removing the O₂ causes the meat to turn purple, but by including carbon monoxide in the package a desirable red color, or the same color as fresh meat, is provided during storage. Woodruff et al. teach treating storing meat in a reduced oxygen modified atmosphere of 0.1-3% CO, with at least 10% CO₂ , or preferably 20-

60% CO₂, 40-80% N₂, and 0% O₂ and convert deoxymyoglobin to carboxymyoglobin on the surface of the meat, wherein the O₂ is removed by evacuation or flushing, as taught by Stockley et al., and further alternatively using a scavenger for a sufficient time period to remove the oxygen (Abstract, Column 1, line 63 to Column 3, line 30). (Abstract, Column 1, line 63 to Column 3, line 30, Examples).

7. Therefore, it would have been obvious to modify the carbon dioxide atmosphere taught by Stockley et al. and include anywhere from 0.1-0.8% carbon monoxide in addition to the carbon dioxide as recited in claims 38,50,55,56,76,85,86,119, 131,136, 137, 138, 150,155,156,157,167,168, since Woodruff et al. teach carbon monoxide at these levels in addition to at least 10% carbon dioxide will provide a desirable red color of fresh meat for meat stored within a low/no oxygen modified atmosphere. It would have been further obvious to combine 0.1-0.8% carbon monoxide to the carbon dioxide/nitrogen mix also taught by Stockley et al. at 40-80% nitrogen, and 20-60% carbon dioxide as recited in claims 49, 83, 131,149, 165 since Woodruff et al. also teach this level of carbon dioxide in combination with a at 40-80% nitrogen/ 20-60% carbon dioxide blend will provide a desirable red color of fresh meat for meat stored within a low/no oxygen modified atmosphere. To use an oxygen scavenger as recited in claims 43,80,124,143,162, would have been an obvious result effective variable of the time allotted to the manufacture to achieve a low oxygen environment since Woodruff et al. teach that obtaining a low oxygen environment may be achieved by a variety of ways such as evacuation and flushing as taught by Stockley, or alternatively with the addition of an oxygen scavenger wherein *sufficient* time is required to deplete the oxygen level.

With respect to forming carboxymyoglobin from deoxymyoglobin or oxymyoglobin, as recited in claims 53,54,134,135,153, and 154, forming the carboxymyoglobin from either would have been an obvious result effective variable of the level of oxygen remaining in the modified atmosphere after flushing since Stockley III et al. teach such packages may contain anywhere from less than 0.5% to less than 0.05% oxygen .

8. Claims 39, 77,120,139,158, are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockley III et al. (US 5686127) in view of Woodruff et al. (US 4522835) as applied to claims 38, 40-56, 76, 78-86, 119, 121, 123-138, 140, 142-157, 159, 161-168 above, further in view of Garwood (US 5629060).
9. Stockley et al. teach an oxygen impermeable second layer peelably adhered to an oxygen permeable first layer covering a meat tray under a modified atmosphere wherein removal of the second layer will result in exposing the meat to atmospheric oxygen, but are silent in teaching a pocket is formed between the two layers.
10. Garwood also teaches an oxygen impermeable second layer peelably adhered to an oxygen permeable first layer covering a meat tray under a modified atmosphere wherein removal of the second layer will result in exposing the meat to atmospheric oxygen. However, Garwood teaches that quite often the first layer is ruptured during the peeling of the second layer, and teaches forming a pocket between the two layers via a rigid second layer a seal strip between the two layers , will minimize contact between the to layers and prevent the chance of rupturing the first layer while removing

the second (Column 1, line 14 to Column 2, line 56, Column 2, line 49-65, Column 5, line 35 to Column 6, line 11).

11. Therefore, it would have been obvious to modify the second layer of Stockley et al. such that a pocket is formed between the first and second layer since Garwood teaches this will prevent rupturing the first layer during the peeling/removal of the second layer when exposing the meat in the tray to the atmosphere.

Declaration filed under 37 CFR 1.132

12. The Declaration filed under 37 CFR 1.132 filed October 14, 2003 is insufficient to overcome the rejections of claims 38-56,76-86,119,-121,123-140,142-159, and 161-168 as set forth in the present Office action because:

(1) The Declaration refers to the FDA regulatory status of applicant's invention, as compared to the conventional use of carbon monoxide in meat packages. However, patent law is independent from FDA regulatory law, as evidenced by issued patents claiming carbon monoxide with meat packages (e.g. Woodruff et al. (US 4522835)) and the Federal Circuit: "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing Scott v. Finney, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir.1994))."

(2) It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that

the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

(3) It include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

13. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

14. Applicant's arguments with respect to not showing a prima facie case of obviousness for the rejections of claims 38-49,51,52,54-56,76-86 under 35 U.S.C. 103(a) as being unpatentable over Woodruff et al. (US 4522835) in view of Sorheim et al. (Meat Science 1999)and Stockley III et al. (US 5686127) and claim 53 under 35 U.S.C. 103(a) as being unpatentable over Woodruff et al. (US 4522835) in view of Sorheim et al. (Meat Science 1999)and Stockley III et al. (US 5686127) further in view of Koch et al (US 3459117) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as set forth above.

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15. Applicant's arguments with respect to the new set of claims 119-121, 123-140, 142-159, 161-168 have been fully considered but they are not persuasive as discussed the rejections above.

16. In response to applicant's argument that since carbon monoxide modified atmosphere meat packaging was not approved by the FDA at the time of the invention carbon monoxide had no utility in meat packaging in the United States. Applicant is reminded that patent law is independent from FDA regulatory law. This issue often is discussed with respect to the determination of pharmaceutical utility (MPEP 2107.01: Section V.):

"FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir.1994)).

The fact that FDA approval is not a prerequisite for finding a compound useful is further, evidenced by Woodruff et al. (US 4522835), who claimed the use of carbon monoxide with modified atmosphere meat packages prior to FDA approval. Thus, FDA approval of carbon monoxide is not relevant to the issue of obviousness.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tada et al. (JP05-319639) also teach adding CO to a meat packages for providing a red color.

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Madsen whose telephone number is (571) 272-1402.

1402. The examiner can normally be reached on 7:00AM-3:30PM M-F.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Madsen
Examiner
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